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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/539,832	02/15/2006	Gerard Marguerie	0617-1002	1147

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EXAMINER	
MYERS, CARLA J	

ART UNIT	PAPER NUMBER
1634	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/539,832	MARGUERIE ET AL.	
	Examiner	Art Unit	
	Carla Myers	1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-21* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-21* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Election/Restrictions

1. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Groups 1-108, claims 1, 2, 5-16, and 18-20 (in part), drawn to nucleic acid methods for identifying a therapeutic agent by assaying for gene expression by detecting nucleic acids. Note that this group includes methods which detect at least 108 different combinations of genes selected from methods which require 2 of the first 3 recited genes, in combination with at least 2 of the 9 additionally recited genes. The first group is considered to be Steoroyl CoA desaturase and Phosphatidic acid phosphate, "eventually in association with" Aldose reducatase and aldehyde reductase and Sphingomyelinase. Upon election of this group, Applicant is required to list the particularly elected combination of genes. Note that this combination may include 2 or 3 genes from the first recited group of 3 genes in combination with 2 (or 3 or 4 or 5 etc) genes from the additionally recited group of 9 genes.

Groups 109-216, claims 1, 2, 5, 11-13, and 6-20 (in part), drawn to protein based methods for identifying a therapeutic agent by assaying for gene expression by detecting proteins. Note that this group includes methods which detect at least 108 different combinations of proteins selected from methods which require 2 of the first 3 recited proteins, in combination with at least 2 of the 9 additionally recited proteins. Group 109 is considered to be Steoroyl CoA desaturase and Phosphatidic acid phosphate, "eventually in association with" Aldose reducatase and aldehyde reductase and Sphingomyelinase. Upon election of this group, Applicant is required to list the particularly elected combination of proteins.

Groups 217-324, claims 3 and 4 (in part), drawn to nucleic acid based methods for diagnosing atherosclerosis or cardiovascular disorders by assaying for gene expression by detecting nucleic acids. Note that this group includes methods which detect at least 108 different combinations of genes selected from methods which require 2 of the first 3 recited genes, in combination with at least 2 of the 9 additionally recited genes. Group 217 is considered to be Steoroyl CoA desaturase and Phosphatidic acid phosphate, "eventually in association with" Aldose reducatase and aldehyde reductase and Sphingomyelinase. Upon

election of this group, Applicant is required to list the particularly elected combination of genes.

Groups 325-432, claims 3 and 4 (in part), drawn to protein based methods for diagnosing atherosclerosis or cardiovascular disorders by assaying for gene expression by detecting protein levels. Note that this group includes methods which detect at least 108 different combinations of proteins selected from methods which require 2 of the first 3 recited proteins, in combination with at least 2 of the 9 additionally recited proteins. Group 325 is considered to be Steoroyl CoA desaturase and Phosphatidic acid phosphate, "eventually in association with" Aldose reducatase and aldehyde reductase and Sphingomyelinase. Upon election of this group, Applicant is required to list the particularly elected combination of proteins.

Groups 433-540, claim 21 (in part), drawn to methods of using a compound for treatment. Note that this group includes methods which use compounds that modulate the activity of at least 108 different combinations of proteins selected from methods which require 2 of the first 3 recited proteins, in combination with at least 2 of the 9 additionally recited proteins. Group 433 is considered to be Steoroyl CoA desaturase and Phosphatidic acid phosphate, "eventually in association with" Aldose reducatase and aldehyde reductase and Sphingomyelinase. Upon election of this group, Applicant is required to list the particularly elected combination of proteins.

2. The inventions listed as Groups 1-540 do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

A 371 case is considered to have unity of invention only when there is a technical relationship among those inventions involving one or more of the same or corresponding technical features. The expression "special technical feature" means those technical features that define a contribution which each of the claimed inventions, considered as a whole, makes over the prior art. In the instant application, the claimed inventions do not share a linking technical feature because the different genes and proteins recited in Groups 1-540 do not share both a common structure and function,

essential to that structure. Each of the recited genes comprises a different nucleotide sequences, has a different specificity of hybridization and encodes for a protein having a different functional property and effect. Each of the recited proteins comprises a different amino acid sequence, has a different molecular weight and has a different biological activity and effect. As the nucleic acids and proteins do not share both a common structure and activity, the nucleic acids and proteins are not considered to be of a 'similar nature' as is required to establish unity of invention. Further, in as much as the technical feature linking inventions 1-540 constitutes the different nucleic acids and proteins recited in the claims, the recited nucleic acids and proteins do not constitute s special technical feature over the prior art because each of the nucleic acids and proteins was known in the art at the time the invention was made. Thus, there is no special technical feature linking the recited groups, as would be necessary to fulfill the requirement for unity of invention.

Additionally, the claimed inventions do not share a linking technical feature because each of the claimed methods involve the use of different reagents, have different outcomes and different effects. The methods of Groups 1-108 require determining the presence of nucleic acid levels and selecting a therapeutic regimen based on the presence of said nucleic acid levels. These steps are not required to practice the method of Groups 109-540. The methods of Groups 109-216 require determining the presence of protein levels and selecting a therapeutic regimen based on the presence of said protein levels. These steps are not required to practice the methods of Groups 1-108 or 217-540. The methods of Groups 217-324 require

determining the presence of nucleic acid levels and diagnosing an individual for atherosclerosis based on the presence of said nucleic acid levels. These steps are not required to practice the methods of Groups 1-216 or 325-540. The methods of Groups 325-432 require determining the presence of protein levels and diagnosing an individual for atherosclerosis based on the presence of said protein levels. These steps are not required to practice the methods of Groups 1-324 or 432-540. The methods of Groups 433-540 require using a compound to treat a disorder by administering a compound to an individual wherein the compound modulates activity of a protein. These steps are not required to practice the methods of Groups 1-432. As such, each of Groups 1-540 have a different objective and outcome and do not share the same corresponding technical feature.

Moreover, methods for screening for compounds that modulate the expression of the genes and proteins recited in claim 1 were known in the art at the time the invention was made. For example, Das (W0 2002/063005; cited in the IDS) discloses methods for screening for compounds that effect the differential expression of phosphatidylinositol specific phosphophilase C in order to identify compounds that could be used to treat cardiovascular disorders, including atherosclerosis (Table 2, pages 36-37). Brownlie (W0 2001/62954; cited in the IDS) discloses methods for screening for compounds that effect the differential expression of human stearoyl-CoA desaturase in order to identify compounds that could be used to inhibit atherosclerosis (pages 5, 19 and 23). In view of the teachings of Das and Brownlie, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have generated a method of screening for

compounds that alter the expression of human phosphatidylinositol specific phosphophilase C and stearoyl-CoA desaturase, in addition to the other nucleic acids and proteins disclosed therein, in order to develop a more sensitive method for identifying therapeutic compounds to treat atherosclerosis.

3. **Further restriction requirement applicable to inventions I and II**

This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The species are as follows:

1) PECAM I; 2) markers of the inflammatory response; 3) TLR4; 4) HSP60; 5) HSP70; 6) Galectin 3; 7) ILI-R; 8) markers of the oxidative stress; 9) HIF-I; 10) Paraoxanase 3; 11) metabolic marker; 12) NADH dehydrogenase; 13) lipoprotein receptors; 14) LDL-R; and 15) VLDL-R

Applicant is required, in reply to this action, to elect a single species to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims

are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Claims 20 encompasses species 1-15.

The following claim(s) are generic: claims 1, 1 and 5-19.

The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons: The recited genes differ from one another with respect to their nucleotide structure and the proteins that they encode. The genes thereby have a different chemical structure and different biological activity. Thus, the claimed genes do not have both a "common property or activity" and a common structure as would be required to show that the inventions are "of a similar nature."

4. Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of

record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103(a) of the other invention.

5. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Carla Myers whose telephone number is (571) 272-0747. The examiner can normally be reached on Monday-Thursday from 6:30 AM-5:00 PM. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla, can be reached on (571)-272-0735.

The fax phone number for the organization where this application or proceeding is assigned is (571)-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at (866)-217-9197 (toll-free).

/Carla Myers/
Primary Examiner, Art Unit 1634